

# DSM Sinochem Pharmaceuticals Spain S.A.



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## Certificate of Analysis

CEFALEXIN MONOHYDRATE

PURILEX ® COMPACTED

Batch/lot: B426386

Batch/lot size: 2700 KG

Manufacturing date: Jul 2014

Expiration Date: Jun 2018

Release date: 09-Jul-2014

Tests	Specifications	Units	Results
Appearance	White-almost white powder with granules		Complies
Solubility	Conforms with test		Complies
Identification (IR)	Conforms with test		Complies
Crystallinity	Crystalline		Complies
pH	4.0 to 5.5		5.0
Specific opt. rotation, anhydrous basis	149 to 158	deg	153
Water content by KF	4.0 to 8.0	%w/w	5.5
Assay, anhydrous basis <sup>1</sup>	97.0 to 102.0	%w/w	100.4
Related Substances:7-ADCA	< = 1.0	%w/w	0.05
Related Substances: PHENYLGLYCINE	< = 1.0	%w/w	< 0.02
Related Substances: PG-AMIDE	< = 0.5	%w/w	< 0.02
Rel. Subst.: ANY OTHER IMPURITY	< = 1.0	%w/w	0.02
Related Substances: TOTAL IMPURITIES	< = 3.0	%w/w	0.20
Bulk Density	> = 0.45	g/ml	0.68
Tapped Density	> = 0.75	g/ml	0.87
Sulphated Ash	< = 0.2	%w/w	Complies if tested**
Residual Acetone	< 0.2	%w/w	Complies if tested**

Pharmacopoeia quality: Complies with the current editions: Ph.Eur, BP, USP, IP.

Manufactured according to ICH Q7 GMP for APIs.

N,N-Dimethylaniline is not used in the manufacturing process of this product or present in any of the raw materials.

DSM order#: 54526

Customer order#: A-2150044

Ship-to: SIEMSGLUSS IBERICA S.A. , Parcela 6, Nave 2, , 08620 , Sant Vicenc Dels Horts (Barcelona) , ES

\*\* Checked at regular intervals

<sup>1</sup>Release Specification

Date of issue: St. Perpetua de Mogoda, February 10, 2015

COA Approved with Digital Signature by Pepita Dalmases, Quality Assurance Assistant, 13:38:18, 10.02.2015

The material covered by this delivery is produced in accordance with DSM Sinochem Pharmaceuticals manufacturing specifications currently in force for this product grade. DSP certifies that the material supplied conforms to the performance typical for this grade and product description, and has been monitored in accordance with the internal quality control routines employed in our company, however, the buyer must check the suitability of this grade for the actual application. This certificate does not release the recipient from his obligation to carry out his usual incoming goods checks. The applicability of any other general terms and conditions is explicitly rejected and superseded by our General Terms and Conditions of Sale as mentioned on our website [www.dsm-sinochem.com](http://www.dsm-sinochem.com)